

Summary of the Proficiency Testing Committee Meeting June 29-30, 1998

The Proficiency Testing Committee of the National Environmental Laboratory Accreditation Conference (NELAC) met on Monday, June 29, 1998, at 1 p.m. Central Daylight Time (CDT) and on Tuesday, June 30, 1998, at 8:30 a.m. CDT as part of the Fourth NELAC Annual Meeting in San Antonio, TX. The meeting was led by its chair, Ms. Anne Rhyne of the Texas Natural Resource Conservation Commission. A list of action items is given in Attachment A. A list of participants is given in Attachment B.

INTRODUCTION

Ms. Rhyne began the meeting by introducing members of the Proficiency Testing Committee. Dr. Bill Gutknecht then described the process for the meeting. Ms. Rhyne summarized the general layout of Chapter 2. Participants received a copy of the current standards and proposed changes in their registration packets. Additional proposed revisions were distributed at the meeting.

Mr. Chuck Wibby described how the proposed revisions were developed. All comments received by the PT Committee since the last annual meeting have been evaluated and discussed. Changes to Chapter 2 and its appendices are a result of those comments.

NELAC has been working with EPA and NIST to achieve consistency and compatibility between the different standards. Language for Interim Standards has been developed (included in the handout). The committee intends for the NELAC standards to eventually cover all analytes.

Mr. Robert Graves announced that copies of the National Standards may be obtained from Mr. Ray Wesselman or Ms. Leigh Corbin, Mr. Wesselman's secretary, at (513) 569-7325. He said that it is about 99% final. Mr. Graves said that at least for the next year or so, the Agency will continue to conduct the effluent study. This is an exception and will not be privatized along with the others.

Ms. Reenie Parris said that January is the target date for having accredited providers. NIST hopes to have their final set of criteria ready next week. NIST has been working on them with the PT Committee. They will be available through Ms. Parris or through the NIST web site.

SECTION 2.0 THROUGH 2.7

Section 2.0

Ms. Rhyne presented a newly revised Section 2.0. This version describes the function of NIST providing NVLAP-based samples on an interim basis. These standards allow NELAC another year to resolve the issue of NIST's role in providing PT samples in other program/matrix/analyte areas.

Ms. Barbara Burmeister lead the discussion of Sections 2.1 through 2.3. Ms. Darlene Raiford led discussions on Sections 2.4 through 2.7. Changes were proposed and accepted throughout the chapter. Discussion regarding specific sections are summarized below.

Section 2.1

A participant asked about the intent of multiple PTOBs. The committee responded that the goal is to have one “PTOB”. However, NIST cannot serve as an oversight board. Therefore NIST will serve as a Proficiency Test Provider Accreditor (PTPA). Currently, no one body is available that can serve all functions of a PTOB. It was noted that the change to PTPA should be made consistently throughout the chapter.

Newly proposed changes to this section were made and accepted. These included changing NELAC program, accreditation, and approval to NELAP program, accreditation, and approval.

Section 2.2.1

After some discussion, it was proposed and accepted that this section be deleted entirely because it does not describe the differences between NELAC and NELAP as the title implies.

Section 2.2.5

This section was renumbered as Section 2.2.4. Discussion ensued about primary accrediting authorities ensuring that labs seeking accreditation are participating in the PT program. The current wording leaves the question of responsibility unanswered; more specific wording is needed. How will the States ensure that the labs are participating? It was noted that States will still be allowed to determine schedules and it is up to them to develop their own system. This is a joint responsibility. In order to clarify the wording, the committee agreed to change “are participating” to “have participated.”

Section 2.3.2

Proposed changes to this section were made and accepted. Additional changes were proposed. An editorial error was noted; the change should be “Samples may not be reused in any subsequent NELAC PT study.” One State representative asked why standards cannot be reused. In response, it was noted that standards in use now will not be NELAC standards in the future.

Section 2.3.2.1

A problem was identified with the wording “all analytes.” There was concern about extremely large numbers of analytes having to be included. In response, it was noted that this refers to those analytes as defined in the National Standards. Laboratories only test for those analytes for which they are seeking accreditation. All analytes of concern are included in the WS program. It becomes a little tricky for the WP. This approach represents a change in philosophy. The absence of an analyte counts as a correct response. One change agreed to was the deletion of “in each sample.”

Section 2.3.3.1

This section was deleted. Acceptance criteria will be determined by regression acceptance criteria. A 20 point minimum is not needed. There are a few analytes that still have statistical limits. Requiring a provider to get “enough customers” is overly restrictive.

Section 2.3.5

The third sentence of this section was reworded to say, “In addition, each provider shall follow procedures and have systems in place that maintain confidentiality and security of all prepared values...”

Section 2.3.6

Proposed changes to this section were made and accepted with the additional change in the first sentence “..the procedures outlined..” to the “..per the requirements..”

Section 2.4, Section 2.4.1

The frequency of twice a year was voted in at NELAC III. Concern was expressed about any required frequency of testing. Changes were proposed that gives the right to have different rates for different programs as would be specified in the appropriate appendix. This is proposed because resources are limited.

Section 2.4.2

It was noted again that field of testing includes program/matrix/analyte. Field of testing can range from a program down to a single analyte. Proposed changes to this section were made and accepted.

Section 2.4.3

A representative from the State of New Jersey questioned whether the language in Section 2.4.3 is too restrictive. He said that different accrediting authorities operate differently. He believes that the NELAC should allow the primary accrediting authorities to operate and administer their programs differently (as best suits them) and let an accrediting authority choose its own provider(s). It was noted that such independence may present a problem with reciprocity. A commentor said that limiting providers would only allow for an even playing field within the restrictive State, and not between States. There was agreement that States must accept data from another provider. The standards were designed so that it should not make a difference to the State if they get reports from different providers. The provider code will be different, but that should be all.

The committee stated that this problem was raised at the interim meeting. It is general consensus that NELAC should not force States to operate in an inefficient mode. It was noted that the experiential history of labs and authorities has been varied. If a State program chooses to select one provider for that State, would that be viewed as more restrictive?

A straw poll was taken among State and Federal representatives. Thirteen of 19 present favored the more restrictive approach. Ms. Rhyne proposed that the issue be tabled. Mr. Wibby modified the proposal, adding an agreement to work with the States to resolve the issue. Ms. Jan Jablonski asked the committee to keep in mind the long-term viability as we head toward externalization. Participants were reminded that the language was already voted in last year. One participant said that the bottom line is that market forces will determine the outcome of this issue. This one sentence affects several other sections. This issue will be addressed further.

Section 2.5

Concern was raised about a laboratory using more than one method and deciding which method to use for PT samples. A committee member said that if a laboratory is certified for more than one method, they should use the most common method. Language proposed to address this was “Use same method as used for routine analysis of that analyte.” It was noted that the program does not call for issuing PTs by method. Because of the costs involved, and because it is not consistent with PBMS, the PT Committee will not issue PT by method (issue by analyte only). It was suggested that labs alternate between methods because they are sometimes forced to change methods in special cases.

Section 2.5.1

Proposed changes to this section were made and accepted. Additional changes included adding “or is accredited” to the end of (b) and changing “and” to “or” in (d).

Section 2.6

This section was deleted.

Section 2.7

This section was deleted, but the title was retained.

Section 2.7.1

Changed “accrediting authority” to “primary accrediting authority.”

Section 2.7.2

According to the committee, routine analyses were intended to be no more than at least 6 months apart. Initial and remedial analyses can be anytime within thirty days. The question is “when does the time clock start?” Language was suggested to deal with this issue. “For initial accreditation or remedial testing, the studies must be at least 30 calendar days apart. For continuing accreditation, completion dates of successive proficiency rounds for a given field of study must be approximately six months apart. Failure to meet the semi-annual schedule is regarded as a failed study after seven months.” This wording was accepted.

Section 2.7.3

Proposed changes to this section were made and accepted. A new change was the wording “and must be at least 30 days apart” added to the end of the last proposed sentence.

Section 2.7.4

Language was added to state that the primary accrediting authority will be notified of investigations and action taken.

There were questions on the issue of re-accreditation. The NELAC Standard mandates that once accreditation is revoked, a lab must pass two samples to be re-accredited (like initial accreditation).

Section 2.7.5

Comment was raised that this may conflict with some language from Chapter 4. There are differences between suspension and revocation. A committee member said that Chapter 4 usually reflects Chapter 2. The committee will table this issue.

Changes included adding “primary” to “accrediting authority,” staying with 60 working days, and ending the last sentence with “for that program and matrix.”

Section 2.7.6

A new section on scheduling was added and accepted.

APPENDIX A

Mr. Tom Coyner reviewed the changes in Appendix A.

General changes: correct references, change “the” to “a” for referencing the “PTOB”, change “sample design” to “sample formulation”, and change “target value” to “prepared value”. Also, there has been clarification of who within NELAC will do things by adding text that specifies the NELAC PT Committee.

There was one comment about the change from working days back to calendar days. The commentor was worried about holidays. The committee said that they had this same concern, but this is a change being made throughout the document.

Section A.3.0

It was asked whether a subcontractor to an accredited provider must also be accredited. The response was that the subcontractor would be approved in the process of approving the provider.

Section A.8.0

Ms. Rhyne said that the committee made an agreement with NIST to delete the time requirement in A.8.0.

Section A.9.2

The following text was proposed by Mr. Tom Coyner and approved by the PT Committee to replace the entire section A.9.2.

“Should a PTOB propose to revoke or suspend a provider’s approval for failure to meet the requirements of these standards, the PTOB shall inform the provider of the reasons for the proposed revocation or suspension and the procedures for appeal of such a decision. The due process rights of the provider shall be protected during any revocation or suspension proceedings. The final decision on the revocation or suspension of a provider’s approval to supply PT samples for the NELAC accreditation program resides with the Executive Director of NELAP. If the provider loses NVLAP accreditation it shall lose NELAP approval to supply samples for the NELAC PT program.”

A commentor remarked that the standards do not address what happens if the provider messes up considerably and causes the user considerable financial harm. Mr. Coyner replied that there may be legal recourse.

APPENDIX B

Mr. Chuck Wibby reviewed the changes in Appendix B.

Section B.1.2

It is the committee's goal to make the NELAC and NIST requirements uniform. The provider will have to meet requirements which are 3 times as stringent as those for the laboratories under test. The committee is waiting on the final changes from NIST to make any further changes to the section.

A question from the floor was raised about the 95% confidence limit in B.2.0. He said that it seems more strict than the 33.3% in B.1.2. Mr. Wibby explained the difference between the stability and homogeneity. The 95% confidence limits are based on ISO guidelines. Ms. Parris said that the ultimate responsibility of the provider is to make sure that they are providing a sample that is fit for intended use.

APPENDIX C

Mr. Matt Caruso reviewed the changes in Appendix C.

Section C.1.1

Mr. Bob Trovato asked whether the regression equations will be based upon data from the actual study or previous EPA data. The committee responded that they are derived from historical data from previous studies. There will be an annual review of these equations by the PT Committee. New data from each year will be incorporated into this review.

40 CFR 141

It was questioned whether to cite specific regulations or leave it general "EPA regulations." If the standards are made specific, these citations will have to be reviewed each year. It was suggested to delete the "guidelines," but keep the reference to "EPA programs". Another comment was that there needs to be consistency throughout the document (referring to Section 2.7). Mr. Tom Coyner suggested some language intended to clarify the adoption of the National Standards and the programs that it covers.

Another commentor asked whether this standard is going to be "laundered" by an administrative lawyer. He said that he's not sure the suggested language is adequate either. Mr. Caruso said that this is one of the reasons why the references to guidelines were eliminated. Ms. Wendy Blake-Coleman said that an EPA lawyer has reviewed the document, however this recent change, of course, has not been reviewed by a lawyer. She said that she is concerned that maybe this is not the section to handle this, but agreed that it needs to be made more clear. States will have to incorporate this into their regulations.

Mr. Wibby clarified the original intent of this section. He said that if we reference the National Standards, then we are covered for all the different possibilities. It is a “blanket”.

Another commentor from the floor said that if the language is adopted, then we are locked in for the entire year. If something else comes up, it cannot be included until the next voting session.

Ms. Darlene Raiford said that if we adopt specifically the 40 CFR 141 we are leaving out WP and the DMR.

Ms. Rhyne clarified the two choices: to adopt Mr. Coyner’s language, which includes reference to the National Standards (as Section 2.1), or to leave the text as it is (more general and open). She stated that the committee had agreed to incorporate the National Standards where applicable into the NELAC Standards. Ms. Rhyne took a vote of the committee. It was agreed to change the language.

Section C.3.0

There was a proposed change on identification of false positives. Other changes included: modify the “note” in C.3.0(c), delete the first two sentences, and modify the last sentence.

Section C.5.3

Discussion of failure rates. It is impossible to give exact rules for failure rates--the standard gives general guidelines. EPA will be running a database, which is part of oversight. NIST will not be the PTOB. Who exactly will be responsible for the role of oversight has not been defined yet. There will be continued discussion on the topic. The Accrediting Authority Committee will establish these kind of pass/fail criteria in the future.

Is there a list or table somewhere that tells the minimum number of analytes per sample?
It is established for WS and WP, but not for others. This list will be further developed in the future.

APPENDIX D

Mr. Chuck Wibby reviewed changes to Appendix D. Most of the changes were editorial. Additional changes were identified as a result of discussions with EPA and NIST.

Section D.2.2

Reference to time lines will be removed.

Section D.2.3

This section will be deleted entirely because NIST cannot send confidential information to clients.

Section D.5.0

The intent of the annual report is to serve as a compendium of all the issues, performance, complaints, etc., so that discussion can take place of changes needed. The annual report will be provided to accrediting authorities.

The electronic bulletin board will provide a list of the providers and accrediting authorities. Information is not public regarding a particular provider. It was asked whether NIST would have to provide information on a provider to a State requesting it, under the Freedom of Information Act. Ms. Parris said that she will have to check on that. Mr. Steve Sweeny said that NIST will not provide this type of information, however summary information will be available in the National Database.

The committee agreed to remove the language “regarding a Provider.” It was then pointed out that the section is redundant with D.8.0 once this text is removed. The committee agreed to delete the entire Section D.5.0.

PTOB to PTPA

It was discussed with NIST and agreed that all PTOB will be changed to PTPA, where applicable. The PT Committee will work with RTI to make the changes where applicable for “PTOB-approved” to “PTPA-approved”. Ms. Parris said that NIST is doing most of these roles of oversight. The issue was mainly a question of semantics. The committee then discussed whether or not a PTOB was needed. It was suggested that PTOB be changed to PTOB/PTPA”. This was agreed on by the committee.

APPENDIX E

Mr. Caruso reviewed changes to Appendix E.

Section E.3.1

Mr. Caruso proposed to change Section E.3.1 on quantitative analyses (SDWA samples) to read, “passing shall be considered as all ten samples having acceptable results.”

Section E.3.2.1

A commentor said that he has a problem with the 20 valid data points. Mr. Caruso replied that this is likely due to a misunderstanding of the nature of the requirement. The microbiological data set is qualitative not quantitative in nature.

Mr. Caruso showed an overhead of analysis of passing rates using various scoring protocols. The basis for the analysis was New York State ELAP’s last ten PTs. The test design was ten samples for the qualitative determination of total coliform and, if present, determination of *E. coli*. Passing rates ranged from 86.4% (for all results correct, EPA, et al.) to 96.9% (8 out of 10 samples correct, OH) for various scoring protocols.

A commentor requested clarification. The committee decided to change the title from “Minimum Laboratory Participation” to “Requirement for Quantitative Data Set Size.”

Corrective Actions

The committee is trying to find something that works for all the States. A commentor voiced concern that the penalty of loss of accreditation after two out of three failed PT tests is a significant increase of the burden placed on laboratories. Ms. Rhyne asked if two consecutive failures would be more acceptable. The reply was no. The committee is trying to avoid the

pattern of pass, fail, pass, fail,... The commentor implied that these standards are unnecessary because the problem is uncommon. Another commentor said that this is not uncommon. The first commentor asked to table the issue. Mr. Wibby said that there is language in Section 2.7 which states that two out of three passing samples is acceptable.

GLOBAL CHANGES

Several global changes were identified and agreed upon. They are:

- change “EPA” to “U.S. EPA”
- change “will” to “shall”
- change “working days” back to “calendar days”
- change “PTOB-approved” to “PTPA-approved”
- change “PTOB” to “PTOB/PTPA”

ACTION ITEMS
Proficiency Testing Committee Meeting
June 29-30, 1998

Item No.	Action Item	Date To Be Completed
1.	N/A	

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Proficiency Testing Committee Meeting
June 29-30, 1998

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